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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,417	11/16/2000	Richard Shimkets	15966-606 (Cura-106)	7720

7590 03/12/2002

MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY and POPEO, P.C
One Financial Center
Boston, MA 02111

EXAMINER
HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
1652	9

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,417	SHIMKETS ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 29 and 32, drawn to an isolated polypeptide compositions and kits comprising said polypeptide, classified in class 530, subclass 350.

II. Claims 5-14, 30 and 33, drawn to an isolated nucleic acid encoding a polypeptide of claim 1, vectors, host cells, compositions and kits comprising said nucleic acid, classified in class 435, subclass 252.3.

III. Claims 15-17, 31 and 34, drawn to an antibody to a polypeptide of claim 1, compositions and kits comprising said antibody, classified in class 530, subclass 387.1.

IV. Claim 18, drawn to a method for determining the presence of a polypeptide of claim 1 in a sample using an antibody to the polypeptide, classified in class 435, subclass 7.1.

V. Claim 19, drawn to a method for determining the presence of a nucleic acid which encodes a polypeptide of claim 1, in a sample using an nucleic acid, classified in class 435, subclass 6.

VI. Claim 20, drawn to a method for identifying an agent that binds to a polypeptide of claim 1, classified in class 435, subclass 7.1.

VII. Claim 21, drawn to a method for identifying a potential therapeutic agent for use in treatment of a pathology which results in the aberrant

expression of the polypeptide of claim 1, classified in class 424, subclass 6.

VIII. Claim 22, drawn to a method for modulating the activity of the polypeptide of claim 1, classified in class 514, subclass 789.

IX. Claims 23, 24, 35 and 42, drawn to a method for treating a pathology associated with a polypeptide of claim 1, comprising administering said polypeptide, classified in class 514, subclass 12.

X. Claims 25, 26 and 36 drawn to a method and a use for treating a pathology associated with a polypeptide of claim 1, comprising administering a nucleic acid, classified in class 514, subclass 44.

XI. Claims 27, 28, 37 and 43, drawn to a method and a use for treating a pathology associated with a polypeptide of claim 1, comprising administering an antibody, classified in class 424, subclass 139.1.

XII. Claims 38 and 39, drawn to a method for screening for a modulator of activity, or of a latency or predisposition to a pathology associated with the polypeptide of claim 1, classified in class 435, subclass 6.

XIII. Claim 40, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of the polypeptide of claim 1 comprising measuring the level of expression of the polypeptide, classified in class 435, subclass 7.1.

XIV. Claim 41, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of the nucleic

acid of claim 5 comprising measuring the level of the nucleic acid in a sample, classified in class 435, subclass 6.

For each of inventions I-XIV above, restriction to one of the following nucleic acids or the encoded protein, (A)-(P), is also required under 35 USC 121. Therefore, election is required of one of inventions I-XIV and one of inventions (A)-(P).

(A). SEQ ID NO: 1 or a sequence encoding SEQ ID NO: 2 (NOV 1).

(B). SEQ ID NO: 3 or a sequence encoding SEQ ID NO: 4 (NOV 2).

(C). SEQ ID NO: 5 or a sequence encoding SEQ ID NO: 6 (NOV 3).

(D). SEQ ID NO: 7 or a sequence encoding SEQ ID NO: 8 (NOV 4).

(E). SEQ ID NO: 9 or a sequence encoding SEQ ID NO: 10 (NOV 5).

(F). SEQ ID NO: 11 or a sequence encoding SEQ ID NO: 12 (NOV 6).

(G). SEQ ID NO: 13 or a sequence encoding SEQ ID NO: 14 (NOV 7).

(H). SEQ ID NO: 15 or a sequence encoding SEQ ID NO: 16 (NOV 8).

(I). SEQ ID NO: 17 or a sequence encoding SEQ ID NO: 18 (NOV 9).

(J). SEQ ID NO: 19 or a sequence encoding SEQ ID NO: 20 (NOV 10).

(K). SEQ ID NO: 21 or a sequence encoding SEQ ID NO: 22 (NOV 11).

(L). SEQ ID NO: 23 or a sequence encoding SEQ ID NO: 24 (NOV 12).

(M). SEQ ID NO: 25 or a sequence encoding SEQ ID NO: 26 (NOV 13).

(N). SEQ ID NO: 27 or a sequence encoding SEQ ID NO: 28 (NOV 14).

(O). SEQ ID NO: 29 or a sequence encoding SEQ ID NO: 30 (NOV 15).

(P). SEQ ID NO: 31 or a sequence encoding SEQ ID NO: 32 (NOV 16).

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(P) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of Group I, the nucleic acid encoding the polypeptide of Group II and the antibody of Group III each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The polypeptide of Group I and the antibody of Group III are each comprised of different amino acid sequences and the nucleic acid of Group II is comprised of a nucleic acid sequence. The nucleic acid has other utility besides encoding protein such as a hybridization probe, and the proteins can be made synthetically. Additionally, the protein can be used to perform specific biological function(s) which are independent of the function(s) of the nucleic acid molecule. The protein has other utility such as for the identification method of Group VI and the antibody can be used for the method of Group IV.

Invention I and Inventions VI and IX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used in a materially different process such as for the synthesis of antibodies to the polypeptide.

The nucleic acid of Group II and the antibody of Group III are distinct from the methods of Groups VI and IX, as the products of Groups II and III are neither made nor used by the methods of Groups VI and IX.

Invention II and inventions V, VII, VIII, X, XII and XIV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide can be used in a materially different process such as one in which the polynucleotide is used to transform a bacterial host cell for heterologous expression and purification of the polypeptide.

The polypeptide of Group I and the antibody of Group III are distinct from the methods of Groups V, VII, VIII, X, XII and XIV, as the products of Groups I and III are neither made nor used by the methods of Groups V, VII, VIII, X, XII and XIV.

Invention III and inventions IV, XI and XIII, are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody can be used in a materially different process such as the isolation of the polypeptide of claim 1.

The polypeptide of Group I and the nucleic acid of Group II are distinct from the methods of Groups IV, XI and XIII, as the products of Groups I and II are neither made nor used by the methods of Groups IV, XI and XIII.

The methods of Groups IV-XIV are independent as they comprise different steps, utilize different products and produce different results.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
March 11, 2002